1.12 510(k) Summary of the *IBD-QUIK CHEK™* test

K030704

The *IBD-QUIK CHEK™* test is a 10-minute immunochromatographic device for the detection of elevated levels of lactoferrin, a marker for fecal leukocytes and an indicator of intestinal inflammation. The test utilizes the same polyclonal antibodies against human lactoferrin as our previously cleared *LEUKO-TEST®* and *IBD-CHEK™* test. The polyclonal antibodies to human lactoferrin are immobilized on nitrocellulose and the conjugate consists of the same antibodies linked to colloidal gold particles. The *IBD-QUIK CHEK™* test results can be used to aid the physician in distinguishing active IBD (inflammatory bowel disease) from active IBS (irritable bowel syndrome - noninflammatory condition).

The *IBD-QUIK CHEK™* test is substantially equivalent to the *LEUKO-TEST®* for the detection of fecal leukocytes and to the *IBD-CHEK®* test for distinguishing active IBD from IBS, targeting the same detection level of lactoferrin. The tests are similar in that all three assays detect the presence of fecal leukocytes. The differences between the assays consist of variations in formats. The *LEUKO-TEST®* is a latex agglutination test, the *IBD-CHEK™* test is an enzyme-linked immunoassay and the *IBD-QUIK CHEK™* test is an immunochromatographic device (lateral flow).

The *IBD-QUIK CHEK™* test was compared directly with the *LEUKO-TEST®*, microscopy and the *IBD-CHEK™* test. When compared with the *LEUKO-TEST®* and microscopy, the *IBD-QUIK CHEK™* test showed a correlation of 97.5%. In the same study, when the *IBD-QUIK CHEK™* was compared to the *LEUKO-TEST®*, the correlation was 88.1%.

In an additional clinical evaluation, the *IBD-QUIK CHEK™* test was compared to clinical assessments and *IBD-CHEK™* test results of IBD patients, active IBS patients and healthy persons. In the IBD group, there were 58 (46 with active Crohn's disease and 12 with active ulcerative colitis) with active disease and 35 with inactive disease. In the active group, 100% tested positive in the *IBD-QUIK CHEK™* test. In the inactive group, 2 (5.7%) of the patients with Crohn's disease tested positive. Of the 46 IBD patients with active Crohn's disease, 100% tested positive. Of the 12 IBD patients with active ulcerative colitis, 100% tested positive in the *IBD-QUIK CHEK™* test. All 17 persons (100%) with active irritable bowel syndrome and all 27 healthy adults (100%) tested negative in the *IBD-QUIK CHEK™* test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
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APR 2 1 2003

David M. Lyerly
Vice President of Research and Development
TECHLABS®, Inc.
1861 Pratt Drive, STE 1030
Corporate Research center
Blacksburg, VA 24060-6364

Re: K030704
Trade/Device Name: *IBS-QUICK CHECK*™
Regulation Number: 21CFR 866.5570
Regulatory Class: Class I
Product Code: DEG
Dated: March 5, 2003
Received: March 6, 2003

Dear Dr. Lyerly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

2.0 STATEMENT OF INTENDED USE

510(k) Number (if known): K030704

Device Name: *IBD-QUIK CHEK*™

Indications For Use:

The *IBD-QUIK CHEK*™ test is an immunochromatographic test for the qualitative detection of elevated levels of lactoferrin, a marker for fecal leukocytes and an indicator of intestinal inflammation. The test can be used as an *in vitro* diagnostic aid to help identify patients with active inflammatory bowel disease (IBD) and rule out those with active noninflammatory irritable bowel syndrome (IBS). FOR *IN VITRO* DIAGNOSTIC USE.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)

J Pierce for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K030704